MAY 3 1 2006

K060707



## B. 510(k) SUMMARY (as required by 21 CFR 807.92)

**Aesculap BiPolar Acetabular Cup**
15 March 2006

**COMPANY:** Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

**ESTABLISHMENT REG. #:** 2916714

**CONTACT:** Matthew M. Hull
610-984-9072 (phone)
610-791-6882 (fax)

**TRADE NAME:** Aesculap BiPolar Acetabular Cup

**COMMON NAME:** BiPolar Acetabular Cup

**CLASSIFICATION NAME:** Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented

**REGULATION NUMBER:** 888.3390

**PRODUCT CODE:** KWY

### SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the *BiPolar Acetabular Cup* is substantially equivalent to the following legally marketed predicate devices:

Biomet Ringloc Bi-Polar Acetabular Component (K051569)

Plus Orthopedics Bipolar Prosthesis CoCrMo (K982447)

Aesculap Excia Total Hip System (K042344)

Aesculap BiContact Hip Stem and Femoral Head (K040191)

### DEVICE DESCRIPTION

The BiPolar cup is a sub-component of an endoprosthetic replacement for the human hip where it assumes the function of the natural femoral head and is combined with a prosthesis head and a hip stem. It consists of a highly polished CoCr shell and a polyethylene insert. In vivo, the shell articulates directly with the well-preserved acetabulum while the insert articulates with a modular head component of a femoral hip. The head is held in place by a retaining ring that is pre-assembled into the insert of the cup. The BiPolar components are available in a variety of sizes to allow the surgeon to rebuild the natural anatomy of the hip joint as accurately as possible while implanting the hemi-arthroplasty.

## INDICATIONS FOR USE

The Aesculap BiPolar Cup is for uncemented use in conjunction with a standard cemented or uncemented femoral replacement implant for the following:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques

## TECHNOLIGICAL CHARACTERISTICS(compared to predicate(s))

This is exactly the same Bipolar cup that was cleared for Plus Orthopedics in 510(k) # K982447 as they are both made by the subcontractor Ortek A.G. in Switzerland. This BiPolar Cup is marketed by Aesculap for use with the femoral components of their previously cleared Excia and BiContact Hip Systems. Just like the Plus and Biomet devices this new Aesculap BiPolar Acetabular Cup will be made with a highly polished Cobalt Chrome alloy (CoCrMo) shell and a polyethylene (UHMWPE) insert. All three devices use a locking ring mechanism, the Aesculap device is the same as the Plus device using a polyethylene ring while the Biomet device uses a metal ring. Both the Aesculap and Plus Bipolar Cups are self-centering as well. The devices are offered to fit either 22 mm or 28 mm heads and are available in a range of outer diameters from 39mm to 60 mm. The Biomet predicate O.D. range is from 41 mm to 70 mm.

## PERFORMANCE DATA

Biomechanical testing was performed to evaluate the effects of destructive forces on the ball/ cup assembly for both head diameters at the extreme size ranges.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2006

Aesculap®,Inc.
c/o Mr. Matthew M. Hull
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K060707/S1
Trade/Device Name: Aesculap BiPolar Acetabular Cup
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWY
Dated: May 11, 2006
Received: May 12, 2006

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

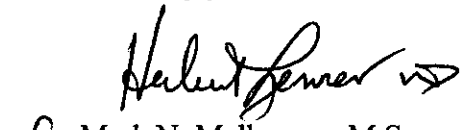
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Mark N. Melkerson, M.S.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## A. INDICATIONS FOR USE STATEMENT

**510(k) Number:** K060707

**Device Name:** ***Aesculap BiPolar Cup***

**Indications for Use:**

The Aesculap BiPolar Cup is for uncemented use in conjunction with a standard cemented or uncemented femoral replacement implant for the following:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques

Prescription Use X and/or Over-the-Counter Use _____

(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K060707